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| EXAMINER | |
|---|---|
| ALEJANDRO, RAYMOND | |
| **ART UNIT** | **PAPER NUMBER** |
| 1745 | |

DATE MAILED: 01/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/960,204 | Applicant(s) VAISNYS ET AL. |
|---|---|---|
| | Examiner Raymond Alejandro | Art Unit 1745 |

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-4,6-8,10 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-8,10 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/14/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/29/04 has been entered.

This submission is being provided in reply to amendment accompanying the foregoing RCE. The applicants have overcome the 35 USC 103 rejection. Refer to the abovementioned amendment for specific details on applicant's rebuttal arguments. However, the double patenting rejection has not been yet overcome and the present claims are newly rejected over art as set forth hereinbelow and for the reasons of record:

### *Double Patenting*

*1.* *It is noted that applicants submitted a terminal disclaimer to obviate the two double patenting rejections set forth in the prior office action of 04/12/04. However, applicants incorrectly identified the patent number from which applicants are disclaiming the terminal part of the statutory term of any patent granted on the instant application. The terminal disclaimer of 07/15/04 incorrectly states patent number 6557102. Nevertheless, the assignee of said patent is not Defibtech LLC having a place of business in Chicago, IL. Further correction or clarification is required in order to overcome this double patenting issue.*

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-3 and 7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 8-9 of U.S. Patent No. 6577102 in view of Adams et al 5372605, and further in view of Wiley et al 5579234. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons:

The US'102 patent claims the following (CLAIMS 1-3 and 8-9):

1. A power supply system for an external defibrillator having a first power supply unit for delivering energy to a patient, and a second power supply unit to power non-energy delivery functions of the external defibrillator, the power supply system comprising:

a first power supply connected to the external defibrillator, wherein the first power supply powers at least a main unit circuit of the external defibrillator to deliver energy to a patient during a first operating mode of the external defibrillator; and

a second power supply, wherein the second power supply powers at least one non-energy delivery circuit during an alternate operating mode, exclusive of a state of the first power supply.

2. The power supply system of claim 1 wherein the non-energy delivery circuit comprises circuitry reporting a status of the external defibrillator.

3. The power supply system of claim 1 wherein the non-energy delivery circuit comprises circuitry sounding an enunciator.

8. The power supply system of claim 1 wherein the non-energy delivery circuit comprises at least one visual indicator.

9. The battery system of claim 8 wherein the visual indicator comprises a light emitting diode.

*In this case, since claim 2 positively recites the presence of a circuitry reporting the status of the external defibrillator, the claim language has been construed as having an indicator to indicate the status of at least a portion of at least the external defibrillator. Thus, the limitation of claim 2 corresponds to an obvious variation of a battery packing having an indicator as instantly claimed in applicants' invention.*

The US'102 patent claims a power supply system according to the foregoing aspects. However, the US'102 patent does not expressly disclose the specific first and second power supply being separated (isolated).

Adams et al disclose a dual battery system for a defibrillator (TITLE) using two separate battery power sources, each having optimized characteristics for monitoring functions and for output energy delivery functions, respectively (ABSTRACT/ COL 2, line 55 to COL 3, line 4/ CLAIM 1). The monitoring functions are supplied electrical power by a first battery source; the output energy delivery functions are supplied by a <u>separate</u> second battery source. The first battery source provides electrical power only to the monitoring functions of the defibrillator (*the non-energy delivery circuit*) and the second battery source provides all of the electrical power for the output energy delivery functions (*the energy delivery circuit*) (ABSTRACT/ COL 2, line 55 to COL 3, line 4/ CLAIM 1).

[57] **ABSTRACT**

**shelf life. The first battery source provides electrical power only to the monitoring functions of the implantable cardioverter defibrillator, and the second battery source provides all of the electrical power for the output energy delivery functions.**

FIG. 2 illustrates a block diagram of the dual battery system 30 for an implantable defibrillator of a preferred embodiment of the present invention. A battery 32 of appropriate voltage and physical size connects to and powers a monitoring circuit 34 only. Another battery 36 of appropriate voltage and physical size connects to and powers the inverter/output circuit 38 only. The moni-

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the present invention where the batteries are rechargeable. A battery 52 of appropriate voltage and physical size connects to and powers a monitoring circuit 54 only. Another battery 60, which is rechargeable and of appropriate voltage and physical size connects to and powers the inverter/output circuit 62 only. Charging of

therapy to two or more implanted electrodes, the improved power system comprising:
first battery means for providing electrical power primarily to the monitoring means;
second battery means for providing substantially all of its electrical power to the output means; and
backup means for allowing the second battery means to provide electrical power to the monitoring means in the event that the first battery means can no longer provide electrical power to the monitoring means.

Adams et al disclose that the first battery source provides electrical power only to the monitoring functions of the implantable cardioverter defibrillator, and the second battery source provides all of the electrical power for the output energy delivery functions (ABSTRACT). Adams et al disclose that a battery 32 or 52 connects to and powers a monitoring circuit 34 or 54 only, respectively. Another battery 36 or 60 connects to and powers the inverter/output circuit 38 or 62 only, respectively (COL 4, lines 54-65/ COL 5, lines 1-12). *Thus, Adams et al clearly envisions having two different and separate power sources for disparate functions.*

In view of these disclosures, it would have been obvious to one skilled in the art at the time the invention was made to employ the specific first and second power supply associated to the main and alternate operating mode of Adams et al in the battery pack of Benvegar et al as Adams et al teaches that with the improved dual battery system configuration the minimum expected monitoring life of an implantable cardioverter defibrillator is independent of the

amount of electrical pulse therapy delivered by the device, such as the number of cardioversion/ defribrillation countershock or the amount of pacing. As a result, the end of the minimum useable lifespan of the first battery source is highly predictable based on steady state current drain calculations. The lifespan of the second source battery is also amenable to calculation based upon the number and amount of energy levels of previously delivered electrical pulse therapies. Accordingly, while a single battery system has proved workable for implantable defibrillators, the use of a single battery system necessarily involves a compromise between the ideal power supply which would otherwise be used for the various types of circuitry within the defibrillator. Hence, it is desirable to provide for an improved dual battery power system for a defibrillator which avoids the need for the compromise required of single battery systems.

Additionally, neither the US'102 patent nor Adams et al'605 expressly disclose specific the indicator to indicate the operative status of the batteries/defibrillator.

Wiley et al disclose a system for automatically testing an electronic device during quiescent periods (TITLE). Wiley et al disclose a portable electronic unit such as a defibrillator including an autotest system for automatically self-testing various electrical components within the unit (ABSTRACT). It includes an auto-test routine that performs an extensive array of rigorous yet time-consuming tests that are impractical to perform during normal modes of operation of the unit (ABSTRACT). The auto-test system provides printout of the results of the carious self-tests performed on the unit, and provides messages on a visual display of any error conditions (ABSTRACT).

In view of the above, it would have been obvious to one skilled in the art at the time the invention was made to use specific indicator to indicate the specific operative status of the

batteries/defibrillator Wiley et al in the combined battery pack of the US'102 patent and Adams et al'605 because Wiley et al disclose that such indicator comprises an auto-test system providing printout of the results of the carious self-tests performed on the unit, and messages on a visual display of any error conditions. Accordingly, if the autotest system detects a needs service malfunction, the operator must acknowledge the error with an input to the unit before the unit enter into its normal mode of operation; also, if the auto-test system detects a service mandatory malfunction, the unit will discontinue any normal mode of operation until the malfunction is corrected. *Thus, such auto-test indicator would assist in determining inadequate performance of the entire battery pack unit and defibrillator.*

### *Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-4, 6-7 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benvegar et al 5721482 in view of Adams et al 5372605 and further in view of Wiley et al 5579234.

The instant application is directed to a battery pack wherein the disclosed inventive concept comprises the indicator feature.

With respect to claim 1:

Benvegar et al disclose an intelligent battery having an advance low battery warning for a battery powered device (ABSTRACT/COL 2, lines 27-45) wherein the battery comprises a battery suitable for powering a battery powered device and a charge monitor circuit. The battery powered device is a defibrillator device (ABSTRACT/COL 18-24). It is disclosed that the charge monitor IC 32 resides on a printed circuit board mounted inside a removable battery pack 12 that is used with the portable defibrillator (COL 4, lines 10-13). The battery powered device is a defibrillator device (ABSTRACT) as well as that the battery powered device is used to treat patients (COL 1, lines 20-24).

Benvegar et al disclose that the high voltage charger circuit 14 contains a large capacitor that is charged by battery pack 12, thereby arming the defibrillator. As will be appreciated by those skilled in the art, the large charge stored on this capacitor is used to shock the patient (COL 3, lines 30-35). *Thus, a second power supply is provided to power at least one-non energy delivery circuit of the battery pack and the external defibrillator.* **Figure 2** above illustrates a diagram of the battery pack 12 wherein the battery pack 12 has a plurality of battery cells 30 (*power supply*) connected in series across the terminals of the battery pack 12 (COL 3, line 65 to COL 4, line 10). *Thus, it is also contended that at least one of the plurality of battery cells can*

*serve as the second power supply as not specific structure of the second power supplied is specified.*

The charge monitor circuit continuously measures the amount of electrical charge input and output from the battery (ABSTRACT/COL 2, lines 27-45). When the amount of charge remaining in the battery goes below a threshold amount an advance low battery warning is generated (ABSTRACT/ COL 2, lines 27-45). It is disclosed that the low battery warning occurs independently of the output voltage of the battery such that an advance low battery warning is provided (ABSTRACT/ COL 2, lines 27-45).

**Figure 2** below illustrates a diagram of the battery pack 12 wherein the battery pack 12 has a plurality of battery cells 30 (*power supply*) connected in series across the terminals of the battery pack 12 (COL 3, line 65 to COL 4, line 10). Also contained within the battery pack 12 is the charge monitor IC 32 which monitors and maintains a cumulative sum of the electrical current as it goes in and out of the battery (i.e. battery cells 30). The amount of charge input into the battery and output from the battery is continuously measured by the charge monitor IC 32 (COL 3, line 65 to COL 4, line 10). It is disclosed that the charge monitor IC 32 resides on a printed circuit board mounted inside a removable battery pack 12 that is used with the portable defibrillator (COL 4, lines 10-13).

It is disclosed that the battery pack 12 (**See *Figure 2 below***) includes a button 34 and an LED bar graph 36 (it is noted that LED stands for light emitting diode). When the button 34 is pressed, charge monitor IC 32 activates LED bar graph 36 which indicates the total charge remaining in the battery cells 30 (COL 4, lines 39-43).

It is disclosed that the charge monitor IC 32 reports information, including the battery state of charge, the battery's temperature and the charge monitor's status including a plurality of calibration and testing flags to the defibrillator/monitor instrument (COL 4, lines 18-23).

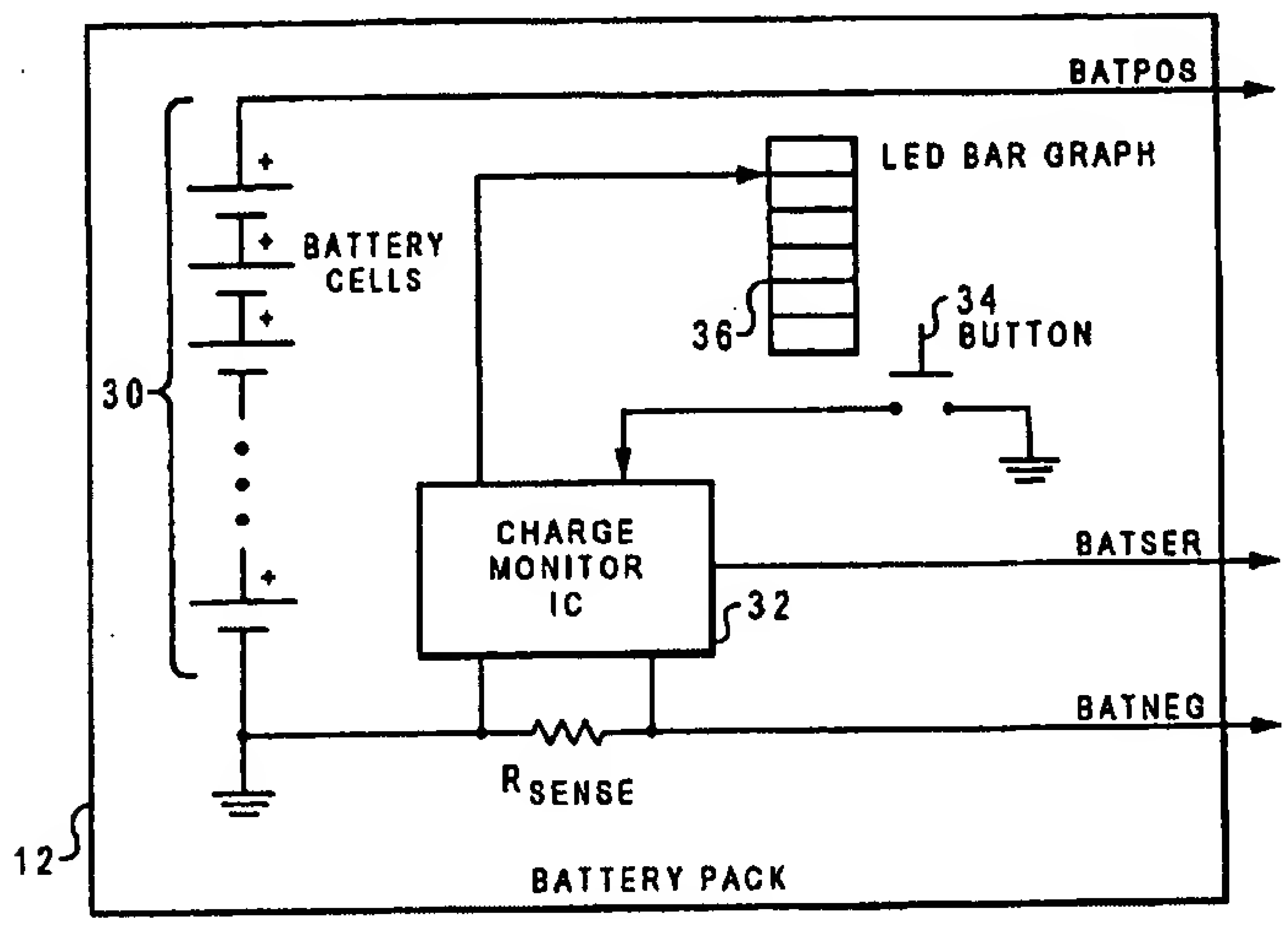



*Fig. 2*

With respect to claims 2-4:

It is disclosed that the battery pack 12 includes a button 34 and an LED bar graph 36 (it is noted that LED stands for light emitting diode). When the button 34 is pressed, charge monitor IC 32 activates LED bar graph 36 which indicates the total charge remaining in the battery cells 30 (COL 4, lines 39-43). *Thus, since the charge monitor IC 32 activates the LED bar graph 36, the LED bar graph 36 (the light emitting diode) flashes to indicate the battery cells are operating properly.*

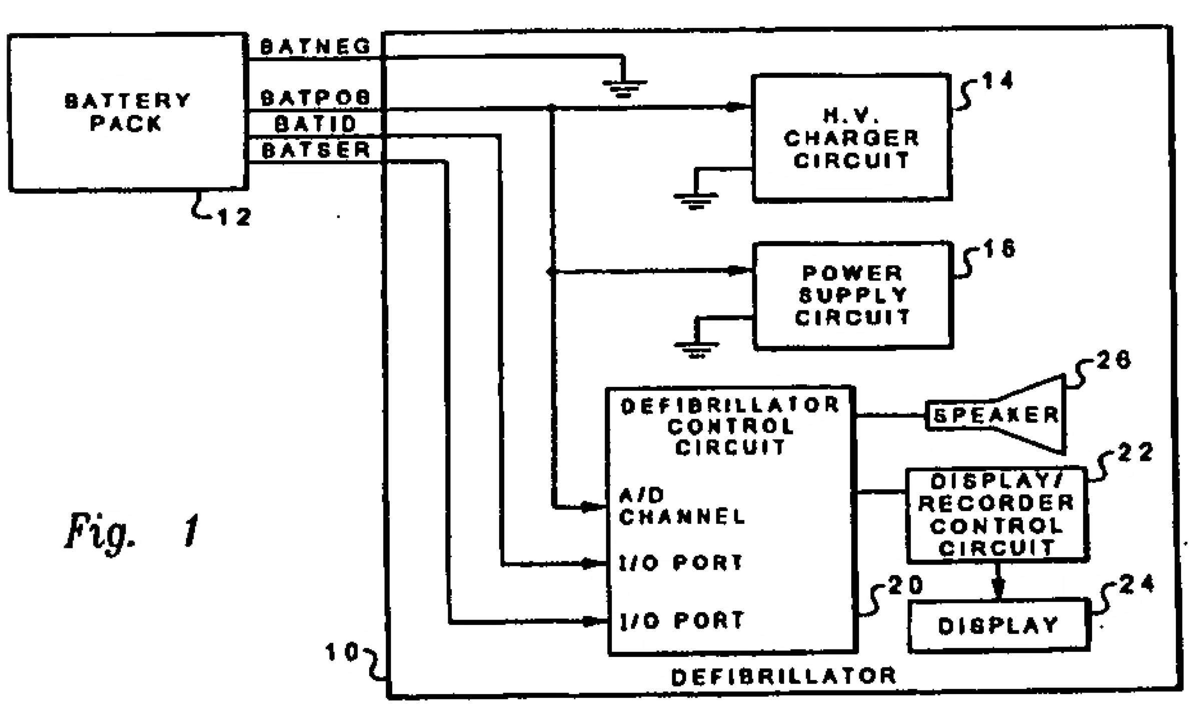
As for claims 6-7, 10-11:

Benvegar et al disclosed that the contrôl circuit is contained within and formed as an integral part of the battery pack, thus, providing an intelligent battery that produces an advance low battery warning for a battery powered defibrillator (COL 7, lines 50-55). It is disclosed that

the control circuit 20 makes a determination of when the amount of charge remaining in the battery goes below a threshold amount, this threshold amount reflects the desired amount of charge to be remaining in a battery. When it is determined that the charge in the battery pack has reached this threshold amount, control circuit 20 provides an advance low battery warning by indicating the low battery condition on display 24 (COL 3, lines 42-55). The control circuit 20 may produce an audio warning that is output by speaker 26. Control circuit 20 also monitors the voltage output of battery pack 12 and when the voltage output reaches a minimum threshold limit, control circuit 20 provides an additional audio and visual warning via speaker 26 and display 24, called a battery shutdown warning which indicates the battery shutdown is imminent (COL 3, lines 55-63).

**Figure 1 below** *shows control circuit feature including the controller, the audio indicator and the enunciator.*

Fig. 1




It is disclosed that the battery pack 12 includes a button 34 and an LED bar graph 36 (it is noted that LED stands for light emitting diode). When the button 34 is pressed, charge monitor IC 32 activates LED bar graph 36 which indicates the total charge remaining in the battery cells 30 (COL 4, lines 39-43). *Thus, the indicator indicates a state of the power supply.* It is taught

that the low battery warning occurs independently of the output voltage of the battery such that an advance low battery warning is provided (ABSTRACT/ COL 2, lines 27-45).

Benvegar et al disclose a battery power source according to the foregoing aspects. However, Benvegar et al do not expressly disclose the specific first and second power supply associated to the main and alternate operating mode, respectively.

Adams et al disclose a dual battery system for a defibrillator (TITLE) using two separate battery power sources, each having optimized characteristics for monitoring functions and for output energy delivery functions, respectively (ABSTRACT/ COL 2, line 55 to COL 3, line 4/ CLAIM 1). The monitoring functions are supplied electrical power by a first battery source; the output energy delivery functions are supplied by a separate second battery source. The first battery source provides electrical power only to the monitoring functions of the defibrillator (*the non-energy delivery circuit*) and the second battery source provides all of the electrical power for the output energy delivery functions (*the energy delivery circuit*) (ABSTRACT/ COL 2, line 55 to COL 3, line 4/ CLAIM 1).

**[57] ABSTRACT**

**shelf life. The first battery source provides electrical power only to the monitoring functions of the implantable cardioverter defibrillator, and the second battery source provides all of the electrical power for the output energy delivery functions.**

**FIG. 2 illustrates a block diagram of the dual battery system 30 for an implantable defibrillator of a preferred embodiment of the present invention. A battery 32 of appropriate voltage and physical size connects to and powers a monitoring circuit 34 only. Another battery 36 of appropriate voltage and physical size connects to and powers the inverter/output circuit 38 only. The moni-**

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the present invention where the batteries are rechargeable. A battery 52 of appropriate voltage and physical size connects to and powers a monitoring circuit 54 only. Another battery 60, which is rechargeable and of appropriate voltage and physical size connects to and powers the inverter/output circuit 62 only. Charging of

therapy to two or more implanted electrodes, the improved power system comprising:
first battery means for providing electrical power primarily to the monitoring means;
second battery means for providing substantially all of its electrical power to the output means; and
backup means for allowing the second battery means to provide electrical power to the monitoring means in the event that the first battery means can no longer provide electrical power to the monitoring means.

Adams et al disclose that the first battery source provides electrical power only to the monitoring functions of the implantable cardioverter defibrillator, and the second battery source provides all of the electrical power for the output energy delivery functions (ABSTRACT). Adams et al disclose that a battery 32 or 52 connects to and powers a monitoring circuit 34 or 54 only, respectively. Another battery 36 or 60 connects to and powers the inverter/output circuit 38 or 62 only, respectively (COL 4, lines 54-65/ COL 5, lines 1-12). *Thus, Adams et al clearly envisions having two different and separate power sources for disparate functions.*

In view of these disclosures, it would have been obvious to one skilled in the art at the time the invention was made to employ the specific first and second power supply associated to the main and alternate operating mode of Adams et al in the battery pack of Benvegar et al as Adams et al teaches that with the improved dual battery system configuration the minimum expected monitoring life of an implantable cardioverter defibrillator is independent of the amount of electrical pulse therapy delivered by the device, such as the number of cardioversion/ defribrillation countershock or the amount of pacing. As a result, the end of the minimum useable lifespan of the first battery source is highly predictable based on steady state current

drain calculations. The lifespan of the second source battery is also amenable to calculation based upon the number and amount of energy levels of previously delivered electrical pulse therapies. Accordingly, while a single battery system has proved workable for implantable defibrillators, the use of a single battery system necessarily involves a compromise between the ideal power supply which would otherwise be used for the various types of circuitry within the defibrillator. Hence, it is desirable to provide for an improved dual battery power system for a defibrillator which avoids the need for the compromise required of single battery systems.

Additionally, neither Benvegar et al'482 nor Adams et al'605 expressly disclose specific the indicator to indicate the operative status of the batteries/defibrillator.

Wiley et al disclose a system for automatically testing an electronic device during quiescent periods (TITLE). Wiley et al disclose a portable electronic unit such as a defibrillator including an autotest system for automatically self-testing various electrical components within the unit (ABSTRACT). It includes an auto-test routine that performs an extensive array of rigorous yet time-consuming tests that are impractical to perform during normal modes of operation of the unit (ABSTRACT). The auto-test system provides printout of the results of the carious self-tests performed on the unit, and provides messages on a visual display of any error conditions (ABSTRACT).

In view of the above, it would have been obvious to one skilled in the art at the time the invention was made to use specific indicator to indicate the specific operative status of the batteries/defibrillator Wiley et al in the combined battery pack of Benvegar et al'482 and Adams et al'605 because Wiley et al disclose that such indicator comprises an auto-test system providing printout of the results of the carious self-tests performed on the unit, and messages on

a visual display of any error conditions. Accordingly, if the autotest system detects a needs service malfunction, the operator must acknowledge the error with an input to the unit before the unit enter into its normal mode of operation; also, if the auto-test system detects a service mandatory malfunction, the unit will discontinue any normal mode of operation until the malfunction is corrected. *Thus, such auto-test indicator would assist in determining inadequate performance of the entire battery pack unit and defibrillator.*

7. Claims 1-4, 6-7 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benvegar et al 5721482 in view of Adams et al 5372605, and further in view of Yerkovich 5983137.

The instant application is directed to a battery pack wherein the disclosed inventive concept comprises the indicator feature.

<u>With respect to claim 1:</u>

Benvegar et al disclose an intelligent battery having an advance low battery warning for a battery powered device (ABSTRACT/COL 2, lines 27-45) wherein the battery comprises a battery suitable for powering a battery powered device and a charge monitor circuit. The battery powered device is a <u>defibrillator device</u> (ABSTRACT/COL 18-24). It is disclosed that the charge monitor IC 32 resides on a printed circuit board mounted inside a removable battery pack 12 that is used with the <u>portable defibrillator</u> (COL 4, lines 10-13). <u>The battery powered device is a defibrillator device (ABSTRACT) as well as that the battery powered device is used to treat patients (COL 1, lines 20-24).</u>

Benvegar et al disclose that the high voltage charger circuit 14 contains a large capacitor that is charged by battery pack 12, thereby arming the defibrillator. As will be appreciated by those skilled in the art, the large charge stored on this capacitor is used to shock the patient (COL 3, lines 30-35). *Thus, a second power supply is provided to power at least one-non energy delivery circuit of the battery pack and the external defibrillator.* **Figure 2** above illustrates a diagram of the battery pack 12 wherein the battery pack 12 has a plurality of battery cells 30 (*power supply*) connected in series across the terminals of the battery pack 12 (COL 3, line 65 to COL 4, line 10). *Thus, it is also contended that at least one of the plurality of battery cells can serve as the second power supply as not specific structure of the second power supplied is specified.*

The charge monitor circuit continuously measures the amount of electrical charge input and output from the battery (ABSTRACT/COL 2, lines 27-45). When the amount of charge remaining in the battery goes below a threshold amount an advance low battery warning is generated (ABSTRACT/ COL 2, lines 27-45). It is disclosed that the low battery warning occurs independently of the output voltage of the battery such that an advance low battery warning is provided (ABSTRACT/ COL 2, lines 27-45).

**Figure 2** below illustrates a diagram of the battery pack 12 wherein the battery pack 12 has a plurality of battery cells 30 (*power supply*) connected in series across the terminals of the battery pack 12 (COL 3, line 65 to COL 4, line 10). Also contained within the battery pack 12 is the charge monitor IC 32 which monitors and maintains a cumulative sum of the electrical current as it goes in and out of the battery (i.e. battery cells 30). The amount of charge input into the battery and output from the battery is continuously measured by the charge monitor IC 32

(COL 3, line 65 to COL 4, line 10). It is disclosed that the charge monitor IC 32 resides on a printed circuit board mounted inside a removable battery pack 12 that is used with the portable defibrillator (COL 4, lines 10-13).

It is disclosed that the battery pack 12 (See ***Figure 2 below***) includes a button 34 and an LED bar graph 36 (it is noted that LED stands for light emitting diode). When the button 34 is pressed, charge monitor IC 32 activates LED bar graph 36 which indicates the total charge remaining in the battery cells 30 (COL 4, lines 39-43).

It is disclosed that the charge monitor IC 32 reports information, including the battery state of charge, the battery's temperature and the charge monitor's status including a plurality of calibration and testing flags to the defibrillator/monitor instrument (COL 4, lines 18-23).

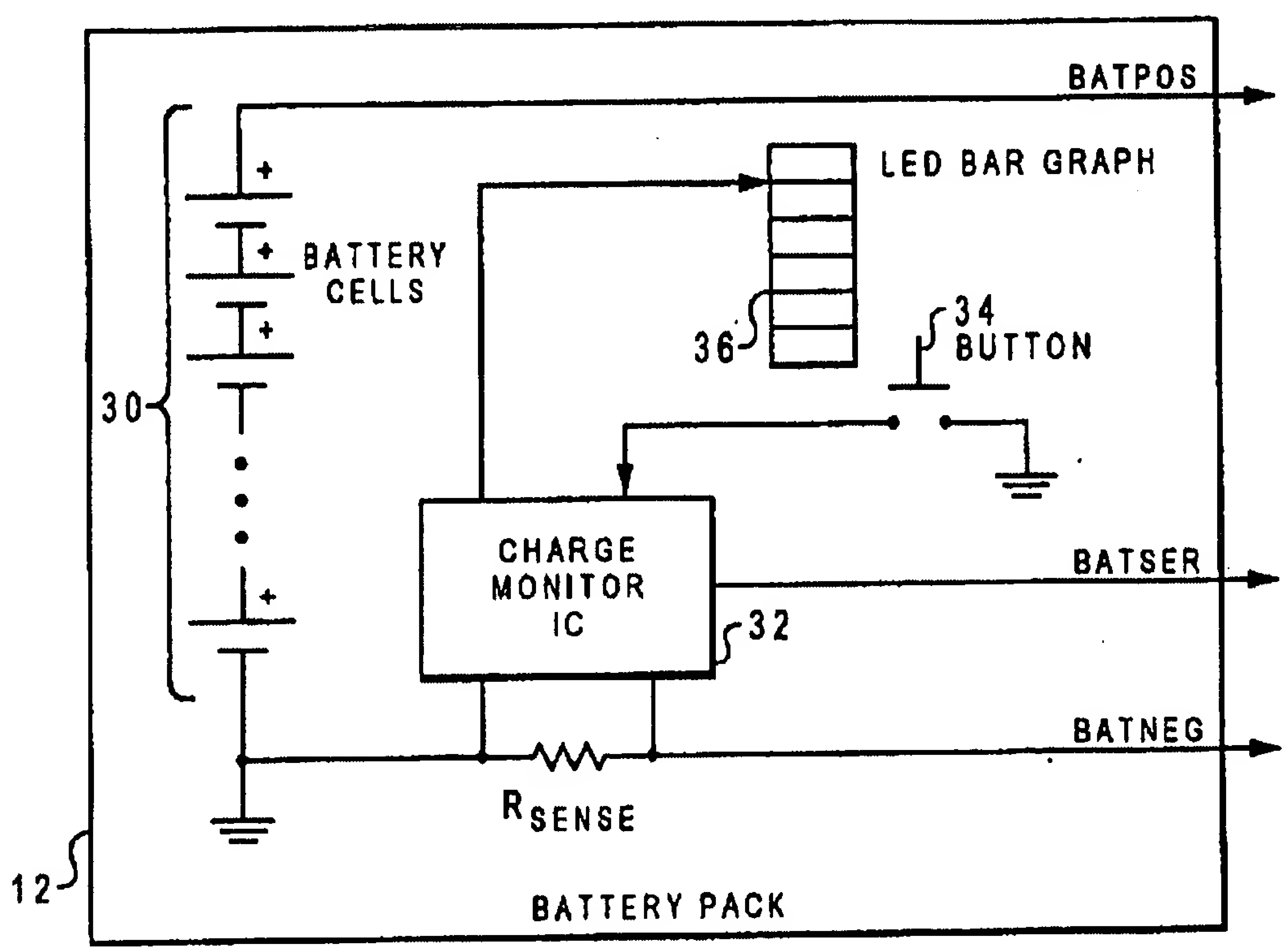


*Fig. 2*

With respect to claims 2-4:

It is disclosed that the battery pack 12 includes a button 34 and an LED bar graph 36 (it is noted that LED stands for light emitting diode). When the button 34 is pressed, charge monitor IC 32 activates LED bar graph 36 which indicates the total charge remaining in the battery cells 30 (COL 4, lines 39-43). *Thus, since the charge monitor IC 32 activates the LED bar graph 36, the LED bar graph 36 (the light emitting diode) flashes to indicate the battery cells are operating properly.*

As for claims 6-7, 10-11:

Benvegar et al disclosed that the control circuit is contained within and formed as an integral part of the battery pack, thus, providing an intelligent battery that produces an advance low battery warning for a battery powered defibrillator (COL 7, lines 50-55). It is disclosed that the control circuit 20 makes a determination of when the amount of charge remaining in the battery goes below a threshold amount, this threshold amount reflects the desired amount of charge to be remaining in a battery. When it is determined that the charge in the battery pack has reached this threshold amount, control circuit 20 provides an advance low battery warning by indicating the low battery condition on display 24 (COL 3, lines 42-55). The control circuit 20 may produce an audio warning that is output by speaker 26. Control circuit 20 also monitors the voltage output of battery pack 12 and when the voltage output reaches a minimum threshold limit, control circuit 20 provides an additional audio and visual warning via speaker 26 and display 24, called a battery shutdown warning which indicates the battery shutdown is imminent (COL 3, lines 55-63).

<u>**Figure 1 below**</u> *shows control circuit feature including the controller, the audio indicator and the enunciator.*

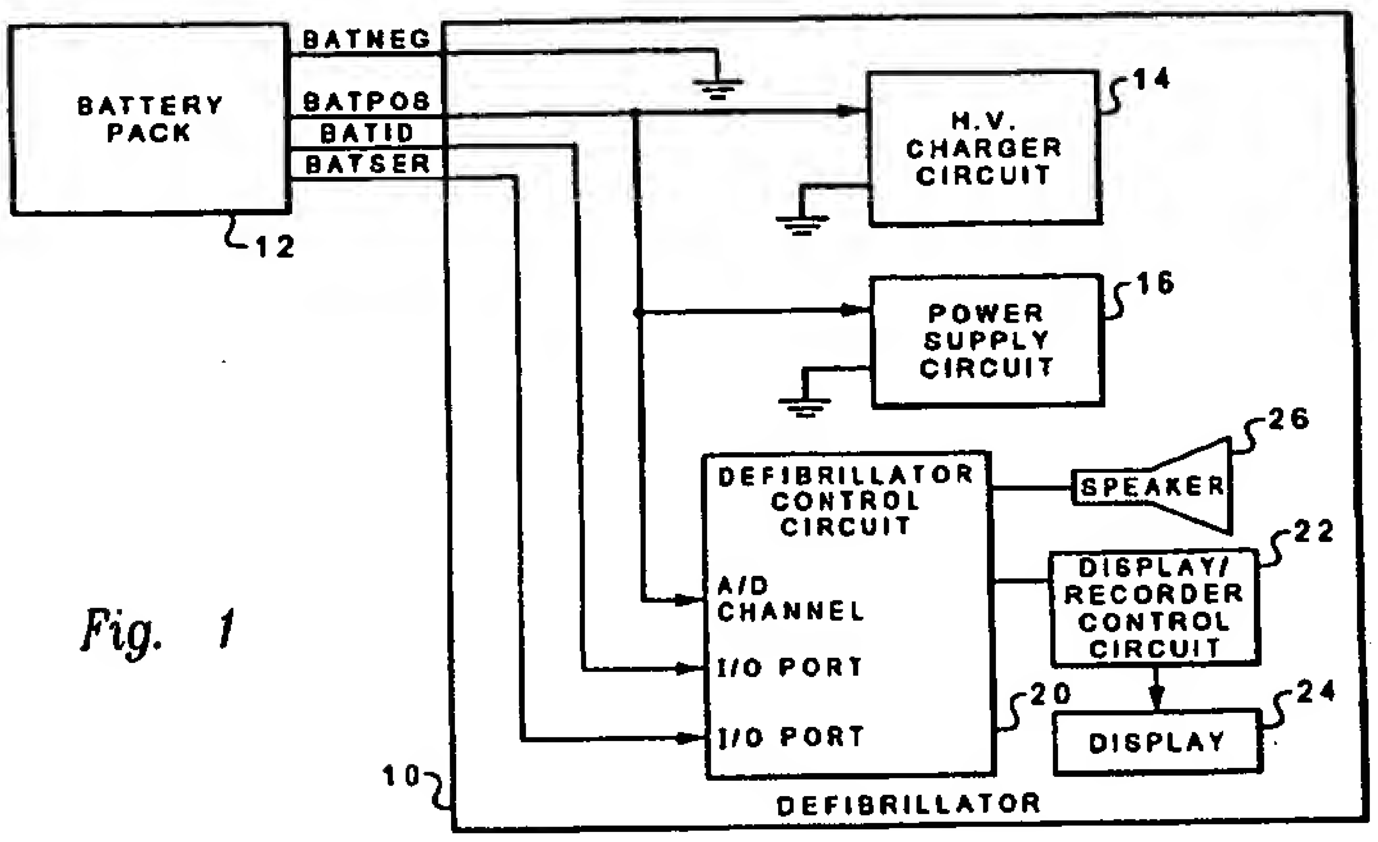


*Fig. 1*

It is disclosed that the battery pack 12 includes a button 34 and an <u>LED</u> bar graph 36 (<u>it is noted that LED stands for light emitting diode</u>). When the button 34 is pressed, charge monitor IC 32 <u>activates</u> LED bar graph 36 which indicates the total charge remaining in the battery cells 30 (COL 4, lines 39-43). *Thus, the indicator indicates a state of the power supply.* It is taught that the low battery warning occurs independently of the output voltage of the battery such that an advance low battery warning is provided (ABSTRACT/ COL 2, lines 27-45).

Benvegar et al disclose a battery power source according to the foregoing aspects. However, Benvegar et al do not expressly disclose the specific first and second power supply associated to the main and alternate operating mode, respectively.

Adams et al disclose a dual battery system for a defibrillator (TITLE) using two separate battery power sources, each having optimized characteristics for monitoring functions and for output energy delivery functions, respectively (ABSTRACT/ COL 2, line 55 to COL 3, line 4/ CLAIM 1). The monitoring functions are supplied electrical power by a first battery source; the output energy delivery functions are supplied by a separate second battery source. The first

battery source provides electrical power only to the monitoring functions of the defibrillator (*the non-energy delivery circuit*) and the second battery source provides all of the electrical power for the output energy delivery functions (*the energy delivery circuit*) (ABSTRACT/ COL 2, line 55 to COL 3, line 4/ CLAIM 1).

[57] **ABSTRACT**

shelf life. The first battery source provides electrical power only to the monitoring functions of the implantable cardioverter defibrillator, and the second battery source provides all of the electrical power for the output energy delivery functions.

FIG. 2 illustrates a block diagram of the dual battery system 30 for an implantable defibrillator of a preferred embodiment of the present invention. A battery 32 of appropriate voltage and physical size connects to and powers a monitoring circuit 34 only. Another battery 36 of appropriate voltage and physical size connects to and powers the inverter/output circuit 38 only. The moni-

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the present invention where the batteries are rechargeable. A battery 52 of appropriate voltage and physical size connects to and powers a monitoring circuit 54 only. Another battery 60, which is rechargeable and of appropriate voltage and physical size connects to and powers the inverter/output circuit 62 only. Charging of

therapy to two or more implanted electrodes, the improved power system comprising:
first battery means for providing electrical power primarily to the monitoring means;
second battery means for providing substantially all of its electrical power to the output means; and
backup means for allowing the second battery means to provide electrical power to the monitoring means in the event that the first battery means can no longer provide electrical power to the monitoring means.

Adams et al disclose that the first battery source provides electrical power only to the monitoring functions of the implantable cardioverter defibrillator, and the second battery source provides all of the electrical power for the output energy delivery functions (ABSTRACT). Adams et al disclose that a battery 32 or 52 connects to and powers a monitoring circuit 34 or 54 only, respectively. Another battery 36 or 60 connects to and powers the inverter/output circuit 38

or 62 only, respectively (COL 4, lines 54-65/ COL 5, lines 1-12). *Thus, Adams et al clearly envisions having two different and separate power sources for disparate functions.*

In view of these disclosures, it would have been obvious to one skilled in the art at the time the invention was made to employ the specific first and second power supply associated to the main and alternate operating mode of Adams et al in the battery pack of Benvegar et al as Adams et al teaches that with the improved dual battery system configuration the minimum expected monitoring life of an implantable cardioverter defibrillator is independent of the amount of electrical pulse therapy delivered by the device, such as the number of cardioversion/ defibrillation countershock or the amount of pacing. As a result, the end of the minimum useable lifespan of the first battery source is highly predictable based on steady state current drain calculations. The lifespan of the second source battery is also amenable to calculation based upon the number and amount of energy levels of previously delivered electrical pulse therapies. Accordingly, while a single battery system has proved workable for implantable defibrillators, the use of a single battery system necessarily involves a compromise between the ideal power supply which would otherwise be used for the various types of circuitry within the defibrillator. Hence, it is desirable to provide for an improved dual battery power system for a defibrillator which avoids the need for the compromise required of single battery systems.

Additionally, neither Benvegar et al'482 nor Adams et al'605 expressly disclose specific the indicator to indicate the operative status of the batteries/defibrillator.

Yerkovich discloses a system for monitoring the condition of a battery pack in a defibrillator (TITLE). In particular, it is disclosed a system for monitoring the capacity of a battery pack capable of delivering current to a load (ABSTRACT). The monitoring system is

connected to the battery pack and monitors voltage of the battery pack. When the monitoring system detects a voltage change indicating depletion of the monitor cell, the monitoring system provides a signal indicative that the battery pack is nearing depletion (ABSTRACT).

In view of the above, it would have been obvious to one skilled in the art at the time the invention was made to use specific indicator to indicate the specific operative status of the batteries/defibrillator Yerkovich in the combined battery pack of Benvegar et al'482 and Adams et al'605 because Yerkovich disclose that such indicator is a system for monitoring the condition of a battery pack in a defibrillator, that is, when the monitoring system (*the indicator*) detects a voltage change indicating depletion of the monitor cell, the monitoring system provides a signal indicative that the battery pack is nearing depletion (ABSTRACT). Hence, the monitoring system (*the indicator*) helps to monitor the actual condition of the battery pack and prevent malfunctioning of the entire battery-defibrillator arrangement.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over: a) Benvegar et al 5721482 in view of Adams et al 5372605 and further in view of Wiley et al 5579234, and/or b) Benvegar et al 5721482 in view of Adams et al 5372605 and further in view of Yerkovich 5983137 as applied to claim 1 above, and further in view of Olson et al 6366809.

Benvegar et al'482-Adams et al'605-Wiley et al'234 and/or Benvegar et al'482-Adams et al'605-Yerkovich'137 are applied, argued and incorporated herein for the reasons above. However, none of the applied references expressly disclose the indicator communicating that the medical device has failed a self test per se.

Olson et al disclose a defibrillator battery with memory and status indication gauge (TITLE/ABSTRACT) wherein a daily self-test and a weekly self-test of the automated external defibrillator (AED) 10 is performed during which the voltage level of battery cells 17 of battery pack 15 is checked; wherein processor 74 illuminates replace battery indicator 64 of status gauge indicator 60 and activates alarm 96 if faults are identified during daily self-test or weekly self-test (COL 6, lines 47-62).

In view of the above, it would have been obvious to one skilled in the art at the time the invention was made to incorporate the indicator communicates that the medical device has failed a self test of Olson et al in the indicator of Benvegar et al'482-Adams et al'605-Wiley et al'234 and/or Benvegar et al'482-Adams et al'605-Yerkovich'137 because Olson et al teach that the battery indicator is illuminated if fault conditions are identified during daily self-test and weekly self-test. Accordingly, the indicator will illuminate if a battery replacement is required. Therefore, the defibrillator battery and associated status indicator insures constant readiness of an automated external defibrillator for defibrillating a patient by preventing defibrillator failure due to an unknown reduced battery charge.

***Response to Arguments***

1. Applicant's arguments with respect to claims 1-4, 6-8 and 10-11 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Alejandro whose telephone number is (571) 272-1282. The examiner can normally be reached on Monday-Thursday (8:00 am - 6:30 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick J. Ryan can be reached on (571) 272-1292. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Raymond Alejandro
Examiner
Art Unit 1745